IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	John W. Swanson	**Art Unit:**	3739
Serial No.:	10/822,491	**Examiner:**	Cohen, L
Filing Date:	April 12, 2004	**Docket:**	MH1.238
Title:	Flexible Bio-Probe Assembly		

DECLARATION UNDER 37 CFR 1.31

I, John W. Swanson, being duly warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 USC 1001) and may jeopardize the validity of the application or any patent issuing thereon, do declare as follows:

I invented the subject matter of U.S. patent application serial number 10/822,491 as defined by the current claims of that application, prior to May 30, 2001. The attached pages are from a final report for a National Institutes of Health (NIH) grant. This report was filed on June 23, 2003, but details work performed during the period from October 1, 1997 to February 28, 2002, as shown on sheet 2. As shown on sheet 5 of the attached sheets, during the course of this work liquid crystal polymer (LCP) was substituted for the originally used polyimide as the brain probe substrate. As a result of substituting the LCP so early, very few polyimide samples were fabricated, a fact that I have confirmed by examining the probes used. All of the ones I have examined were made with LCP. I recall fabricating probe assemblies from LCP only shortly (3 months at most) after beginning to fabricate these assemblies. I have been able to determine the date on which I first began to fabricate brain probe assemblies by finding the shipping label from the first mask that I received from our vendor, which is attached with the date omitted, to preserve information confidential to the assignee of the present application. I swear that the date is well prior to May 30, 2000 (one year before the critical date of May 30, 2001). Accordingly, I can be certain that I reduced-to-practice a brain probe fabricated using LCP well before the May 30, 2001 critical date.

I have searched my laboratory notebooks for the period in question and did not find a reference to the substitution of LCP for polyimide. My thought is that I was so busy with so many aspect of this project and several others that I had accepted responsibility for during this period that I simply failed to make a laboratory notebook entry for the innovation in question.

All statements in this declaration made of my own knowledge are true. All statements made on the basis of information and belief and believed to be true.

John W. Swanson April 25, 2005
John W. Swanson Date

MASTER PLATE

WORKING PLATE

Image Technology, Inc.
621 San Antonio Rd., Palo Alto, CA 94306
FAX 494-2971
415-494-3113

CUSTOMER Bioelectric

NUMBER MASK 22 REV

LAYER EMULSION

GLASS TYPE CHROME X

IRON OXIDE

CD REQUESTED

CD MEASURED

INSPECTED DATE:

DEVICE Bioelectric	STEP DATE 10/20/00
MASK	
SUB NUMBER 10862	OPERATOR LM
INSPECTOR LM	STACKER —
C.D. CLEAR	OPAQUE

10/822,491; Declaration Under 37 CFR 1.131
Attached Sheet1: Shipping Label of Probe

microHelix

NIH / NINDS Grants Office
Neuro Science Center
6001 Executive Blvd.
Room 3290 MSC-9531
Bethesda, MD 20892-9531

June 23, 2003

Dear Sirs:

We are pleased to submit two copies of our Phase II final report entitled "Investigator Ready, Interconnected Microprobe Systems; 2R44-NS33427-02A1. This grant was quite successful in the development of a novel high-density connector and may offer applications in several industries. MicroHelix is interested in continuing efforts in this area to expand application utility while reducing cost for medical research as well as commercial application.

We look forward to further work in this exciting area.

Sincerely,

John Swanson

John Swanson
Sr. Materials Scientist
MicroHelix, Inc.
503-495-2308

NINDS final report cover letter

Attached Sheet 2:
Cover Letter For Grant Report

Final Report
SBIR Phase II Grant

Investigator Ready, Interconnected Microprobe Systems (Grant # 2R44-NS33427-02A1)

Project Scope

The purpose of the project, funded under the auspices of an NIH SBIR Phase II grant, has been to investigate the feasibility and develop a zero insertion force high density percutaneous connector and cable system (including a front-end high gain amplifier) utilizing microelectrode probes, lead wires and percutaneous connectors to record neural activity inside the body. High failure rates of current microprobe systems result primarily from ill-suited interconnect systems and inadequate termination, cleaning and encapusulating processes and techniques. This development effort would capitalize on photolithographic based flex film in combination with laser micro-machining processes and cabling process to produce a investigator-ready microprobe systems suitable for a wide range of neurological testing activities. It was anticipated that this program would develop an enabling technology that is expected to contribute to neurological research as well as medical intervention. This novel high-density connector technology may also see applications extending beyond the medical fields.

The work conducted during Phase I & II of the project demonstrates that the high density zero insertion force percutaneous connector concept is sound, and can be fabricated consistently and in mass. Several completed interconnected microprobe systems were built by PI Medical (the silicon based probes by the University of Michigan).

Grant Dates

Phase I of this grant commenced August 1,1995 and ended February 29, 1996. The final report for Phase I was submitted along with the Phase II application. Funding for the first year of Phase II began October 1, 1997. A progress report for the first year's work was submitted in 1998. Personnel changes, as well as the challenging nature of the project, necessitated extensions that were allowed by the granting agency. Consequently, the grant ended February 28, 2002.

Key Personnel

Key personnel and the percent effort spent on the project are listed below:

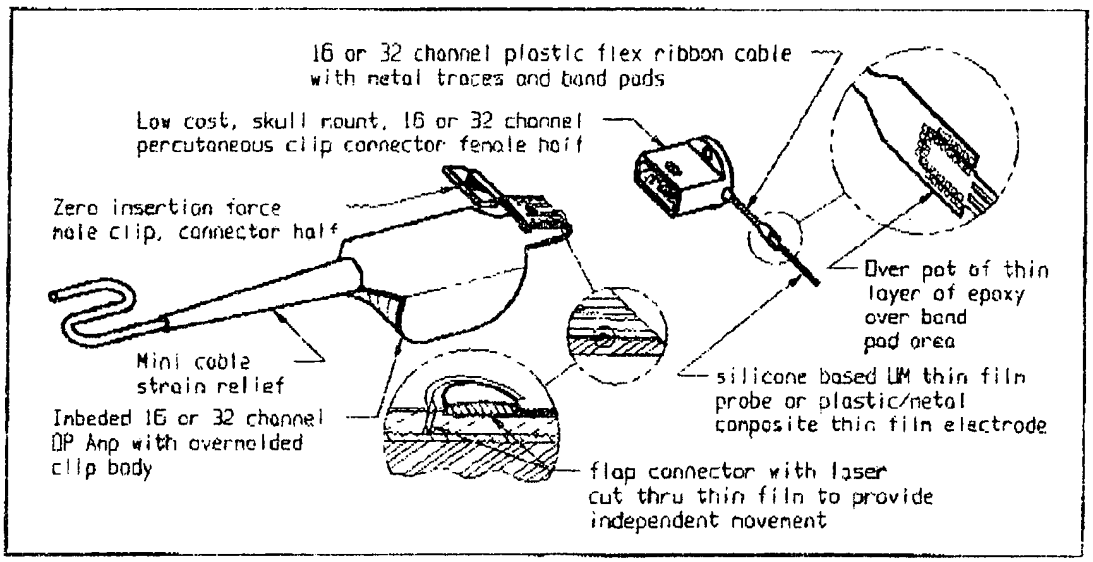
Name	Role in Project	Percent of Hours
John Swanson	PI	44
Bob Lucas	Lab Technician	12
Sergey Varivoda	Laser Technician	12
Homar Cisneros	Lab Technician	12

PI Medical proposed to do the following in Phase II:

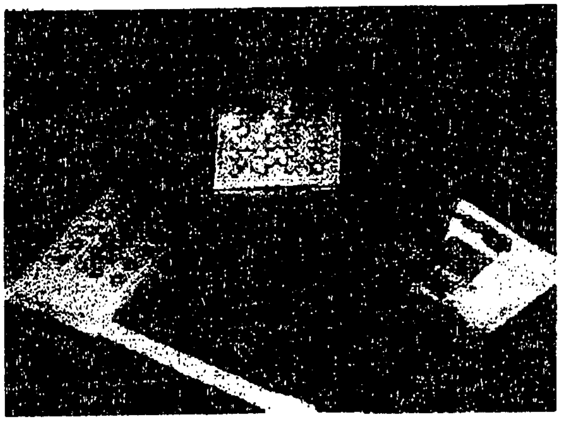
1. Define the microprobe system requirements.
2. Produce conceptual designs.
3. Standardize and select UM probe configurations.
4. Design microprobe systems.
5. Optimize cable and interconnect design.
6. Fabricate micro-cable and intermediates.
7. Fabricate microprobe systems
8. Activate microprobe systems
9. Characterize microprobe systems
10. Source microprobes from U. of Mich.
11. Design and fabricate packaging and ship. Config.
12. Researcher evaluation of probe systems
13. Final Report

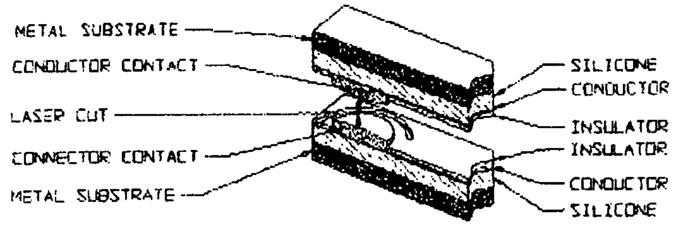
Concept and Implementation

The project was split primarily between three distinct development areas; fine trace flex film, cable and connector housing, and unity gain amplifier. The fine trace flex film is a single component consisting of bond pads on one end, contact pads on the other end and fine traces connecting the bond pads to the contact pads. The bond pads, on the flex film, connect the University of Michigan silicon based probes using typical wire bonding techniques. The contact pads, on the flex film, terminate in the connector body and makeup the actual connector contacts, which eliminates additional connector mating components and bonding. The traces on the flex film between the contacts and the bond pads are parallel to create a micro-ribbon cable providing both small size and flexibility. The female connector halve is a single component metal body containing the flex film contacts. The flex film micro-ribbon cable and bond pads extend out of the metal body through a small side port. The mating (male) halve of the connector is essentially a spring clip with a mating flex film contact system adhered and opamps mounted to the back-end of the spring clip. The cable assembly is connected and extends from the back-end of the opamps. Since the system design was sound, little rework was required.



Flex film construction and implementation
The flex film substrate was originally polyimide. However, it was replaced by liquid crystal polymer (LCP) based on its dimensional and hydrolytic stability. The connection concept was found to operate successful. Concept shown below.





The opamps were bonded to the metal connector housing. Wires were terminated to the opamps; followed by potting (using a UV acrylated epoxy) and overmolding using a low durometer black silicone. Both strain relief and flex relieves were included in the connector design.